U.S. Food and Drug Administration
Administrative Practices and Procedures; Formal Evidentiary Public Hearing

OMB Control No. 0910-0191

SUPPORTING STATEMENT **Part A: Justification**

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA, us or we) regulations. The Administrative Procedures Act (5 U.S.C. 553(e)) provides that every Agency shall give an interested person the right to petition for issuance, amendment, or repeal of a rule. Section 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371) states that Agencies shall give interested and affected persons an opportunity to participate in and present their views in a formal evidentiary hearing, either personally or through a representative.

We therefore request extension of OMB approval for the information collection provisions under 21 CFR Part 10: *Administrative Practices and Procedures*, under 21 CFR Part 12: *Formal Evidentiary Public Hearing*, and discussed in this supporting statement.

2. Purpose and Use of the Information Collection

The presiding officer and other participants use the information collected to identify specific interests to be presented in a hearing. This preliminary information serves to expedite the pre-hearing conference and commits participation. In accordance with 21 CFR 12.45(e) the presiding officer may omit a participant's appearance.

3. Use of Improved Information Technology and Burden Reduction

FDA is considering developing ways individuals can submit petitions for notice of participation in hearings electronically.

4. Efforts to Identify Duplication and Use of Similar Information

No duplication of effort by Federal Agencies has been identified and there is no similar data that can be used or modified for use.

5. Impact on Small Businesses or Other Small Entitites

No small businesses will be involved in this information collection.

6. Consequences of Collecting the Information Less Frequently

There are no legal obstacles to reduce the burden.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances for this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

8a. Publication in the FEDERAL REGISTER

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the Federal Register of February 22, 2018 (83 FR 7742). Although one comment was received, it was not responsive to the four collection of information topics solicited and therefore will not be discussed in this document.

9. Explanation of Any Payment or Gift to Respondents

No gift or payment is provided to respondents to the information collection.

10. Assurance of Confidentiality Provided to Respondents

No assurance of confidentiality has been provided except as provided in 21 CFR 20.61 and generally considered in reviewing data and information submitted to FDA. Notices received by the Agency are publicly available.

11. Justification for Sensitive Questions

The information collection contains no questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

The total annual estimated burden imposed by this collection of information is 12 hours annually.

Table 1.--Estimated Annual Reporting Burden[1]

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
10.30-- Citizen Petition	207	1	207	24	4,968
10.33--Administrative reconsideration of action	4	1	4	10	40
10.35--Administrative Stay of Action	5	1	5	10	50
10.85--Advisory Opinions	4	1	4	16	64
12.22--Filing Objections and Requests for a Hearing on a Regulation or Order	3	1	3	20	60
12.45--Notice of Participation	4	1	4	3	12
Total					5,194

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no capital, start-up, operating or maintenance costs associated with this collection.

14. Annualized Cost to the Federal Government

The estimated cost to the Federal government is that incurred in reviewing the notice of participation, as well as preparing the Agency's response. The Agency estimates that the cost of a fully supported professional employee (GS-13/5) required to review such notices is $52.66 per hour.

21 CFR Section	Total Hours	Total Cost to Federal Government
10.30-- Citizen Petition	4,968	$261,615
10.33--Administrative reconsideration of action	40	$2,106
10.35--Administrative Stay of Action	50	$2,633

10.85--Advisory Opinions	64	$3,370
12.22--Filing Objections and Requests for a Hearing on a Regulation or Order	60	$3,160
12.45--Notice of Participation	12	$632
TOTAL		$273,516

15. Explanation for Program Changes or Adjustments

    We retain the currently approved burden estimate for the information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

    There are no plans to publish this collection of information.

17. Reason(s) for Display of OMB Expiration Date is Inappropriate

    FDA will display the OMB expiration date as required by 5 CFR 1320.5.

18. Exceptions to "Certification for Paperwork Reduction Act Submissions"

    There are no exceptions to the certification.